

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 03/30010

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L31/10 A61L31/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,Y	WO 00 32255 A (SCIMED LIFE SYSTEMS INC) 8 June 2000 (2000-06-08) claims 1,2,4,8,10 page 5, line 26-28 page 11, line 17-29 page 13, line 19,20 page 14, line 9,10 page 17, line 11-27 page 21, paragraphs 14-21	1-25
X,Y	US 6 368 658 B1 (KAMATH KALPANA ET AL) 9 April 2002 (2002-04-09) claim 21 example 7 column 4, line 30-39,54-56 column 7, line 3-9,20-32 --- -/--	1-25

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

12 February 2004

Date of mailing of the international search report

24/02/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Peris Antoli, B

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,Y	US 5 824 048 A (TUCH RONALD J) 20 October 1998 (1998-10-20) claims 1-8 column 3, line 6-22 column 6, line 33-65 example 8	1-25
X,Y	WO 93 06792 A (SCIMED LIFE SYSTEMS INC) 15 April 1993 (1993-04-15) claims 1,2,4 page 19, line 24 -page 21, line 9	1-25
X,Y	WO 00 45734 A (WRIGHT MEDICAL TECH INC) 10 August 2000 (2000-08-10) claims 1,4-8 page 1, line 28-33 page 3, line 27-32 page 5, line 29-33	1-25
X,Y	WO 02 26139 A (CORDIS CORP) 4 April 2002 (2002-04-04) example 4 figures 4,5 page 8, line 15,16 page 20, line 1-16	1-25
Y	DUNNE M ET AL: "Influence of particle size and dissolution conditions on the degradation properties of polylactide-co-glycolide particles" BIOMATERIALS, ELSEVIER SCIENCE PUBLISHERS BV., BARKING, GB, vol. 21, no. 16, August 2000 (2000-08), pages 1659-1668, XP004200585 ISSN: 0142-9612 page 1659, column 2, paragraph 2 -page 1660, column 1, paragraph 1	1-25
Y	JAIN R A: "The manufacturing techniques of various drug loaded biodegradable poly(lactide-co-glycolide) (PLGA) devices" BIOMATERIALS, ELSEVIER SCIENCE PUBLISHERS BV., BARKING, GB, vol. 21, no. 23, 1 December 2000 (2000-12-01), pages 2475-2490, XP004216917 ISSN: 0142-9612 page 2476, column 1, paragraph 5 -column 2, paragraph 2	1-25

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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
Although claim 11 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☒ Claims Nos.: 1-25 (partially)
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 1-25 (partially)

Present independent claims 1, 11 and 12 relate to coating(s) which are defined by reference to a desirable characteristic or property, namely (i) "coating having at least two layers, each of them having at least one physical property affecting the releaseability of a therapeutic compound, said property differing from one to the other layer" 'see claim 1!;

(ii) "controllable drug releasing gradient coating" 'see claim 11!; and

(iii) "first (coating) layer having at least one physical property affecting the releaseability of a therapeutic compound, and at least one additional layer differing in said at least physical property" 'see claim 12!.

The dependent claims 5-6 or 17-18 indicate one physical property of the coating layers -namely, the molecular weight-, and claims 7 or 19 indicate various kinds of polymers of which at least one of the layers could be constituted. However, none of the claims gives a concrete definition of both coating layers.

The claims cover all coating layers having the aforementioned characteristics or properties, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT only for theoretical examples of said layers. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the coating layers by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Consequently, the search has been carried out for those parts of the claims which appear to be clear, namely medical implants comprising anti-restenotic drugs as defined in claims 8-10 or 21-25.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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